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Editorial

Endovascular Aortic Aneurysm Repair – Still a Failed Experiment?

Endovascular aneurysm repair [EVR] has been described as unethical, financially unviable and a 'failed experiment'.[1] Although the uptake of EVR has flourished with a robust evidence base, there remains concern regarding long-term viability, fed by the long-term outcome data from the EVAR-1 trial.[2] The authors reiterated the early survival advantage following EVR compared to open surgery [OR] (adjusted odds ratio for EVR vs. OR, 0.39; 95% confidence interval [CI], 0.18 to 0.87; $P = 0.02$) but highlighted the 8-year follow-up data as demonstrating that EVR is associated with increased rates of graft-related complications, re-interventions and cost despite similar aneurysm-related mortality (adjusted hazard ratio, 0.92; 95% CI, 0.57 to 1.49; $P = 0.73$). These long-term results of EVAR-1 have been lauded by endovascular sceptics as a failure of the technology. Furthermore, additional subgroup analysis from EVAR-1 has described significant numbers of aortic ruptures with associated mortality.[3] It would appear, from EVAR-1 trial data, that the catch up in aneurysm-related mortality in the EVR group is due to the development of endograft-related complications and rupture. It remains imperative that endovascular techniques should be robustly evaluated, but the question as to whether open surgery or endovascular repair offers the "best approach" is too simplistic, especially for patients deemed unfit for OR.

The findings reported in EVAR-1 raise questions regarding the relevance of historical clinical trials in guiding modern day vascular practice. We would argue that it is time to move on from the EVAR-1 trial and the interpretation of the long-term results in favour of OR. While representing the best clinical trial of its kind, it is now a historical study which was never powered to investigate the longer term outcomes. Vascular clinical practice has changed dramatically, as have our understanding of the role of surveillance and re-intervention.

Firstly, the provision of service has changed. Vascular units have reconfigured with a drive towards centralised arterial surgery, the highest volume centres producing the best results despite more complex case mix. Units recruiting patients to EVAR-1 qualified having performed as few as 20 cases. The learning curve is recognized as much longer. To be considered 'well-trained' a unit should have performed 55–60 cases.[4] It could be argued that the complexities of care in the follow-up period are not truly appreciated until several hundred patients have been treated.

Secondly, vascular surgeons have clearer understanding of endovascular techniques with enhanced quality control, surveillance regimens and appreciation for when and how to intervene. EVAR-1 reported a 23.1% re-intervention rate. Units with large EVR experience have demonstrated this does not translate to current practice reporting re-intervention rates as low as 7.4%.[5] Type II endoleaks are benign, type IV are obsolete, and modern practice utilising graft consignments and 3-D rotational imaging means every effort is made to ensure no patient leave the operating suite with a type I or III endoleak. At least 81.5% of the graft ruptures that occurred in EVAR-1 and subsequent aneurysm-related mortality could have been avoided with current practice, as demonstrated in our own units unpublished data of 0.897 aortic deaths per 100 patient years following 478 cases.

Finally, device technology has evolved rendering the EVAR-1 devices outmoded and data from long-term follow-up inconsequential. Improved neck fixation and iliac limb conformity have reduced type I endoleaks and graft migration. Lower-profile devices with lubricious delivery systems have extended the eligibility to patients with difficult access. In EVAR-1 morphological eligibility was 43%. With current device 'instructions for use', it is 80%. Current peri-operative EVR mortality in these more challenging populations remain vastly superior to OR [1.2% vs. 4.8%, $P < 0.001$].[6]

The shift towards an endovascular-dominated practice is multifactorial, combining clinical factors, scientific progress and patient choice. When provided with the evidence, patients prefer EVR because of the over-riding benefit in early survival and reduced risk of organ dysfunction.[7] Patients are willing to travel to centralised units, to receive EVR with the added incentives of survival and prompt restoration of quality of life.[8] Sceptics often fall back on the argument of cost yet EVAR-1 presents an unfair and inaccurate comparison between EVR and OR. There is no record of laparotomy-related complications and associated costs. Surveillance post EVR has been rationalised to duplex and may yet become more patient-specific, reducing this burden further.

EVR is certainly not a failed experiment; and represents the principle driver for reduced AAA mortality. Patients will vote with their feet and seek out EVR rather than expose themselves to the unnecessary peri-operative risk associated with OR. The tables have surely turned. Given the evidence, considering the risks, if morphologically suitable the authors could not consent to OR and are astonished that so many patients still do.

References

1 Collin J, Murie JA. Endovascular treatment of abdominal aortic aneurysm: a failed experiment. *Br J Surg* 2001;**88**(10):1281–2.
2 Greenhalgh RM, Brown LC, Powell JT, Thompson SG, Epstein D, Sculpher MJ. Endovascular versus open repair of abdominal aortic aneurysm. *N Engl J Med* 2010;**362**(20):1863–71.
3 Wyss TR, Brown LC, Powell JT, Greenhalgh RM. Rate and predictability of graft rupture after endovascular and open abdominal aortic aneurysm repair: data from the EVAR trials. *Ann Surg* 2010;**252**(5):805–12.
4 Forbes TL, DeRose G, Kribs SW, Harris KA. Cumulative sum failure analysis of the learning curve with EVARr. *J Vasc Surg* 2004;**39**(1):102–8.

1078-5884/$ – see front matter
doi:10.1016/j.ejvs.2012.03.013

5 Black SA, Carrell TW, Bell RE, Waltham M, Reidy J, Taylor PR. Long-term surveillance with computed tomography after endovascular aneurysm repair may not be justified. *Br J Surg* 2009;**96**(11):1280–3.
6 Schermerhorn ML, O'Malley AJ, Jhaveri A, Cotterill P, Pomposelli F, Landon BE. Endovascular vs. open repair of AAAs in the Medicare population. *N Engl J Med* 2008;**358**(5):464–74.
7 Winterborn RJ, Amin I, Lyratzopoulos G, Walker N, Varty K, Campbell WB. Preferences for endovascular (EVAR) or open surgical repair among patients with AAAs under surveillance. *J Vasc Surg* 2009;**49**:576–81.
8 Holt PJ, Gogalniceanu P, Murray S, Poloniecki JD, Loftus IM, Thompson MM. Screened individuals' preferences in the delivery of AAA repair. *Br J Surg* 2010; **97**(4):504–10.

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